In re Application of James E. Hildreth

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I. AMENDMENTS

Please cancel claim 48 without prejudice, amend claims 37 and 40, and add new claims 59 to 61, as indicated below. Upon entry of the present amendment, the status of the claims will be as follows:

- 1. (Previously presented) A method of reducing the risk of transmission of a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a composition consisting essentially of a β -cyclodextrin, wherein said β -cyclodextrin reduces the risk of transmission of the pathogen.
 - 2. (Original) The method of claim 1, wherein the pathogen is an enveloped virus.
- 3. (Original) The method of claim 2, wherein the enveloped virus is an immunodeficiency virus, a T lymphotrophic virus, a herpesvirus, a measles virus, or an influenza virus.
- 4. (Previously presented) The method of claim 2, wherein the enveloped virus is a human immunodeficiency virus.
- 5. (Original) The method of claim 2, wherein the enveloped virus is a *Herpes simplex* virus.
 - 6. (Original) The method of claim 1, wherein the pathogen is a microbial pathogen.
- 7. (Original) The method of claim 6, wherein the microbial pathogen is a bacterium, a yeast, or a protozoan.

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8. (Original) The method of claim 6, wherein the microbial pathogen is a Chlamydia spp., a Trichomona spp., or a Candida spp.

- 9. (Previously presented) A method of reducing the risk of a subject becoming infected with a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen in the subject with an effective amount of a pharmaceutical composition consisting essentially of a β-cyclodextrin, wherein said β-cyclodextrin reduces the risk of the subject becoming infected with the sexually transmitted pathogen.
 - 10. (Original) The method of claim 9, wherein the subject is a human.
- 11. (Original) The method of claim 9, wherein the cells susceptible to infection by the pathogen are epithelial cells.
- 12. (Original) The method of claim 11, wherein the epithelial cells are vaginal epithelial cells or rectal epithelial cells.
- 13. (Original) The method of claim 8, wherein the pharmaceutical composition is formulated in a solution, a gel, a foam, an ointment, a cream, a paste, or a spray.
- 14. (Original) The method of claim 9, wherein the pharmaceutical composition is formulated in a suppository, a film, a vaginal disk, or a condom.

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15. (Original) The method of claim 9, wherein the β -cyclodextrin is 2-hydroxypropyl- β -cyclodextrin.

16 to 18. (Canceled)

19. (Original) The method of claim 9, wherein the sexually transmitted pathogen is an enveloped virus or a microbial pathogen.

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- 20. (Original) The method of claim 19, wherein the enveloped virus is an immunodeficiency virus, a T lymphotrophic virus, a herpesvirus, a measles virus, or an influenza virus.
- 21. (Original) The method of claim 10, wherein the sexually transmitted pathogen is a human immunodeficiency virus (HIV) or a *Herpes simplex* virus.
- 22. (Original) The method of claim 19, wherein the microbial pathogen is a bacterium, a yeast, or a protozoan.
- 23. (Previously presented) A method of reducing the risk of transmission of a sexually transmitted disease by a subject infected with a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a pharmaceutical composition consisting essentially of a β -cyclodextrin, wherein said β -cyclodextrin reduces the risk of transmission of the sexually transmitted disease by the subject.
 - 24. (Original) The method of claim 23, wherein the subject is a vertebrate.

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- 25. (Original) The method of claim 23, wherein the cells susceptible to infection comprise a secretion produced by the subject.
- 26. (Original) The method of claim 25, wherein the secretion is semen or a vaginal secretion.
- 27. (Original) The method of claim 23, wherein the cells susceptible to infection are epithelial cells.
- 28. (Original) The method of claim 23, wherein the pharmaceutical composition is formulated in a solution, a gel, a foam, an ointment, a cream, a paste, or a spray.
- 29. (Original) The method of claim 23, wherein the pharmaceutical composition is formulated in a suppository, a bioadhesive polymer, a vaginal disk, or a condom.
- 30. (Original) The method of claim 23, wherein the β -cyclodextrin is 2-hydroxypropyl- β -cyclodextrin.
 - 31 to 32. (Canceled)
- 33. (Original) The method of claim 23, wherein the sexually transmitted pathogen is an enveloped virus or a microbial pathogen.

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34. (Original) The method of claim 33, wherein the enveloped virus is an immunodeficiency virus, a T lymphotrophic virus, a herpesvirus, a measles virus, or an influenza virus.

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- 35. (Original) The method of claim 24, wherein the sexually transmitted pathogen is a human immunodeficiency virus (HIV) or a *Herpes simplex* virus.
- 36. (Original) The method of claim 33, wherein the microbial pathogen is a bacterium, a yeast, a mycoplasma, or a protozoan.
- 37. (Currently amended) A pharmaceutical composition consisting essentially of a concentration of 1 mM to 100 mM β -cyclodextrin, which reduces the risk of transmission of a sexually transmitted pathogen.

38 to 39. (Canceled)

- 40. (Currently amended) A composition for reducing the risk of transmission of a sexually transmitted disease, the composition consisting essentially of a β-cyclodextrin[[,]] and a solid substrate and, optionally, wherein, optionally, the composition contains an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof.
- 41. (Original) The composition of claim 40, wherein said the solid substrate comprises an organic polymer.

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- 42. (Original) The composition of claim 41, which is a condom, a diaphragm, a vaginal disk, or a vaginal film.
 - 43. (Original) The composition of claim 41, which is a glove.
- 44. (Original) The composition of claim 40, wherein the solid substrate is an absorptive substrate.
 - 45. (Original) The composition of claim 44, which is a sponge or a tampon.
- 46. (Previously presented) The pharmaceutical composition of claim 37, which is formulated in a solution, a gel, a foam, an ointment, a cream, a paste, a lubricant, a jelly, or a spray.
- 47. (Previously presented) The pharmaceutical composition of claim 37, which is formulated in a suppository, a film, a sponge, a condom, a bioadhesive polymer, a diaphragm, a glove, a pellet, a tablet, or a tampon.
 - 48. (Canceled)
- 49. (Previously presented) The pharmaceutical composition of claim 37, wherein the β -cyclodextrin is in a concentration of 5 mM to 30 mM.
- 50. (Previously presented) The composition of claim 40, wherein the β -cyclodextrin is present in an amount of 0.1 grams to 2 grams.

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- 51. (Previously presented) The composition of claim 40, wherein the β -cyclodextrin is present in an amount of 0.25 grams to 0.75 grams.
- 52. (Previously presented) The method of claim 9, further comprising contacting the pathogen or cells susceptible to infection with the pathogen with a composition consisting essentially of a contraceptive, an antimicrobial agent, an antiviral agent, a lubricant, or a combination thereof.
- 53. (Previously presented) The method of claim 52, wherein the contraceptive is a spermicide.
- 54. (Previously presented) The method of claim 52, wherein the antimicrobial agent is an antibiotic.
- 55. (Previously presented) The method of claim 23, further comprising contacting the pathogen or cells susceptible to infection by the pathogen with a composition consisting essentially of an antimicrobial agent, an antiviral agent, or a combination thereof.
- 56. (Previously presented) The method of claim 55, wherein the antimicrobial agent is an antibiotic.

57 to 58. (Canceled)

59. (New) A composition consisting essentially of about 0.1% to 3% β-cyclodextrin and a solid substrate, wherein, optionally, the composition contains an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof.

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- 60. (New) The pharmaceutical composition of claim 59, which is formulated in a suppository, a film, a sponge, a condom, a bioadhesive polymer, a diaphragm, a glove, a pellet, a tablet, or a tampon.
- 61. (New) A composition consisting essentially of about 0.1% to 10% β -cyclodextrin and a solid substrate, wherein, optionally, the composition contains an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof.